

## Special 510(k) Summary

Special 510(k) Number: \_\_\_\_\_

Date Prepared: April 23<sup>rd</sup>, 2009

This Special 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

- A. Submitter:  
MedShape Solutions, Inc. (MSS)  
1575 Northside Drive, Suite 440  
Atlanta, Georgia 30318
- B. Company Contact:  
Jack Griffis  
Vice President, Research & Development  
(404) 249-9156 x11 (direct)  
(404) 249-9158 (fax)  
[Jack.Griffis@MedShapeSolutions.com](mailto:Jack.Griffis@MedShapeSolutions.com)
- C. Device Information:  
Trade Name: *WedgeLoc™ 180X Suture Anchor with Opti-Fiber™ Sutures*  
Common Name: Suture Anchor
- D. Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue  
HWC/MBI 21 CFR 888.3040  
Suture, Nonabsorbable, Synthetic, Polyethylene  
GAT 21 CFR 878.500
- E. Predicate Device(s):  
MSS, *WedgeLoc™ Suture Anchor with Opti-Fiber™ Suture*, K083792  
Arthrex PushLock™ Suture Anchor, K051219  
Arthrex FiberWIRE™ Polyblend Suture, K021434
- F. Labeling and Intended Use:  
NOTE: Draft labels and instructions for use can be found in Attachment D. However, no changes to the labeling or Instructions for Use have been made to the original submitted information per K083792.

The proposed *WedgeLoc™ 180X Suture Anchor and Opti-Fiber™ Suture* has the same intended uses as the previously cleared device (K083792). In particular, both devices are indicated for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair

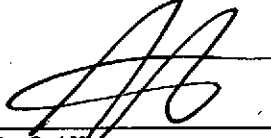
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction

G. Substantial Equivalence Summary:

The proposed *WedgeLoc*<sup>TM</sup> 180X Suture Anchor is substantially equivalent to the predicate *WedgeLoc*<sup>TM</sup> Suture Anchor with *Opti-Fiber*<sup>TM</sup> Suture (K08379) and the Arthrex PushLock<sup>TM</sup> Suture Anchor (K051219) in which the basic features and intended uses are the same. In addition, the technological characteristics of the *WedgeLoc*<sup>TM</sup> 180X and the *WedgeLoc*<sup>TM</sup> Suture Anchors are equivalent. Any differences between the *WedgeLoc*<sup>TM</sup> 180X Suture Anchor and the predicate *WedgeLoc*<sup>TM</sup> or Arthrex PushLock<sup>TM</sup> Suture Anchors are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, MedShape Solutions, Inc. has determined that the new *WedgeLoc*<sup>TM</sup> 180X Suture Anchor is substantially equivalent to the currently marketed predicate device.

 04/23/2009  
\_\_\_\_\_  
Jack Griffiths  
Vice President, Research & Development



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 16 2009

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

MedShape Solutions  
% Jack Griffis  
1575 Northside Drive, Suite 440  
Atlanta, Georgia 30318

Re: K091202

Trade/Device Name: WedgeLoc™ 180x Suture Anchor and Opti-Fiber™ Sutures  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC, MBI, GAT  
Dated: September 2, 2009  
Received: September 4, 2009

Dear Mr. Griffis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

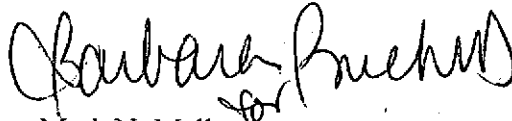
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K091202

Device Name: *WedgeLoc*<sup>™</sup> 180X Suture Anchor and *Opti-Fiber*<sup>™</sup> Sutures

### Indications for Use:

The MedShape Solutions, Inc., *WedgeLoc*<sup>™</sup> 180X Suture Anchor with *Opti-Fiber*<sup>™</sup> Sutures are intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
- Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]* for *MXM*  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K091202